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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,431	07/25/2000	Bernard Belleau	IAFG 12 RE	3925

23599 7590 03/29/2005

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/585,431

Applicant(s)

BELLEAU ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/084,222.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

The references cited on the attached form PTO-892 (5 pages), except for the Higgins reference cited on page 5, are those references which were cited during the prosecution of U.S. Application Serial No. 08/084,222 (now U.S. Patent No. 5,532,246), of which the present application is a reissue. Accordingly, additional copies of the previously cited references have not been provided to Applicants.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for the treatment of a hepatitis B virus infection in a mammal/human suffering therefrom, does not reasonably provide enablement for the treatment, in general, of a mammal/human suffering from hepatitis B virus infection where the therapeutic objective to be achieved in such mammal/human is not specified. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The present claims lack a recitation of a therapeutic objective to be achieved by the administration of the claim specified compound in a mammal/human suffering from hepatitis B infection. Therefore, the claims encompass the treatment of the host for *any and all* therapeutic purposes. The art, however, is currently unaware of any agent, or

Art Unit: 1614

combination of agents, which is effective for treating any and all disease conditions, i.e., a panacea. Lacking knowledge of such, practicing the claimed method in the manner disclosed by Applicants would not imbue the skilled artisan with a reasonable expectation that any and all disease conditions could be treated in a mammal by the mere consumption of the claim designated compound(s). Given that the art fails to recognize, and Applicants have failed to demonstrate, that any and all disease conditions could be treated in a mammal through the administration of the claim designated compound, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that the claim designated compound could serve as a panacea is doubted in light of Higgins (cited by the Examiner on the attached form PTO-892 at page 5). Higgins addresses the administration of interferons in the treatment of infections. The reference is therefore deemed analogous to the subject matter disclosed and claimed by Applicants. Higgins state “Interferons have proved to be

Art Unit: 1614

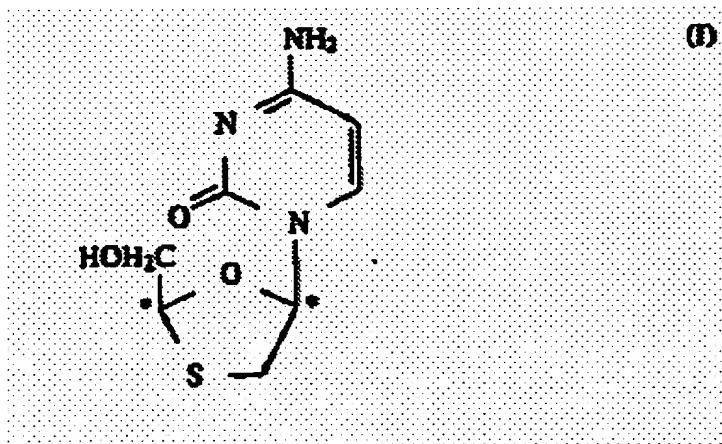
more complicated substances than they first appeared to be but, so far have failed to live up to the, probably over enthusiastic and optimistic, role envisaged for them in clinical medicine. There can be no doubt that interferon *is not the panacea many believed it could be.*" (emphasis added)(page 116, col. 1, first section of first full paragraph).

While the reference does not expressly state that in the field of viral infection treatment, the art is unaware of a panacea, the teaching nevertheless serves as a basis for the Examiner's doubt that the presently claimed compound could, in fact, treat any and all diseases in a mammal/human infected with hepatitis B.

Suggestion for Overcoming the Above Rejection

In order to overcome the above rejection, Applicants should amend the claims in the following manner (claim 1 is here used as an example):

1. A method for the treatment of hepatitis B infection, in a mammal, including a human, suffering from hepatitis B infection, comprising administering an effective amount of a compound of formula (I)



or a pharmaceutically acceptable salt, ester, or salt of an ester thereof to said mammal.


None of the claims are allowed.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J. Henley III
Primary Examiner
Art Unit 1614

March 23, 2005